

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/455,975	05/31/95	RUBIN	J 40399/299/NI

026633 HM12/0613
HELLER EHRMAN WHITE & MCAULIFFE
815 CONNECTICUT AVE
WASHINGTON DC 20006

EXAMINER

SAOUD, C

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/455,975

Applicant(s)
RUBIN et al.

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 17, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-45, 49-55, 57-119, 121, 123-126, 128, 129, and 131-149 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-45, 57-62, 64-86, 88, 89, 91-109, 111-119, 132, 133, 136, 137, ^{40-147, 149} is/are allowed.
- 6) ☒ Claim(s) 49-55, 63, 87, 110, 121, 123-126, 128, 129, 131, 134, 135, 138, ^{139, 148} is/are rejected. OK 6/13/01
- 7) ☒ Claim(s) 90 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

DETAILED ACTION

Transitional After Final Practice

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 17 April 2001 has been entered.

Response to Amendment

2. Claims 46, 47, 48, 56 and 120 have been canceled, claims 38, 49, 57, 73, 82, 114, 121, 126, 129, 133, 135, 137, 139 and 141 have been amended and claims 142-149 have been added as requested in the amendment of paper #30, filed 17 April 2001. Claims 38-45, 49-55, 57-119, 121, 123-126, 128-129, and 131-149 are pending in the instant application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed 17 April 2001 have been fully considered but they are not deemed to be persuasive.

Double Patenting

6. Claim 55 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 50. Claim 90 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 88. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. Claims 63 and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using KGF and KGF polypeptides which have an amino acid sequence as set forth in Figure 7, or is truncated within the region of amino acids 32-78, does not reasonably provide enablement for using a segment that comprises amino acids 32-64 of Figure 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The method of the claims requires the polypeptide (or segment) to have a particular activity of stimulating endothelial cells. The instant claims only require the structure of amino acids 32-64 of Figure 7 based on the recitation of "comprising amino acids 32-64 of Figure 7". The instant claims fail to recite sufficient structure to provide for the function required in the

claims. The instant specification fails to provide guidance on how to use a polypeptide with as few amino acids as recited in the claims for stimulating endothelial cells and the specification establishes that these amino acids are not sufficient for the recited activity. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, absent evidence to the contrary.

Applicant's arguments have been considered, and although the majority of the claims have been amended to avoid the previous grounds of rejection, the amendments fail to place the above claims in condition for allowance for the reasons presented above.

8. Claims 49-55, 110, 121, 123-126, 128-129, 131, 134-135, 138-139, and 148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in paper #20 as applied to claims 49-56, 82-110, and 121-131.

Applicant argues that it was within the skill of the art to determine what amount of KGF would be required to accelerate or improve the healing of a wound. This argument is not persuasive because the instant specification fails to teach such an activity, provides no examples with regard to wound healing, improvement or acceleration, and the art is silent to the protein of the instant claims. There is no guidance in the prior art nor in the specification, and the claims fail to recite sufficient method steps to achieve the claimed outcome. A review of the Wands factors

demonstrates that the instant specification is deficient and does not enable the methods as claimed, absent evidence to the contrary.

With regard to the methods of inhibiting KGF activity by administration of an antibody to KGF, Applicant argues that "it is not necessary under U.S. Patent law to exemplify the invention". Applicant is correct, however, in view of the lack of examples, the lack of a disclosure of a blocking antibody, the prevalence of prior art that teaches that use of antibodies in a therapeutic manner is unpredictable, lack of a distinct protocol for treatment, it would require undue experimentation to practice the invention as claimed. Applicant cites Alarid et al. as evidence that KGF-neutralizing monoclonal antibodies can be used to inhibit KGF *in vivo*. However, the specifics of Alarid et al. which resulted in the generation and production of KGF-neutralizing monoclonal antibodies is not found in the instant specification as filed, nor is the method which was used by Alarid et al. which produced the *in vivo* result. The claims must recite sufficient elements and steps for achieving the claimed method; without knowing what amount to administer and for what length of time, one of ordinary skill in the art would not be able to practice the invention as claimed. (See *In re Colianni* (CCPA) 195 USPQ 150.)

Applicant's citation of Weiner is noted, however, Weiner is representative of the state of the art at the time of the instant invention, therefore, it is not found persuasive for overcoming the instant grounds of rejection.

Allowable Subject Matter

9. Claims 38-45, 57-62, 64-86, 88-89, 91-109, 111-119, 132-133, 136-137, 140-147, 149 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 8, 2001

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud